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## Animal Biotech Policy and Research in the EU

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### Report Highlights:

Regulation of animal biotechnology in Europe parallels regulation of plant biotechnology, both at the EU level and, to a large extent, at the Member State (MS) level. At present, reports indicate that there are no commercial applications of animal biotech in the EU, nor have there been any notifications of food use. MS approaches to research vary widely, with most permitting laboratory projects for medical or pharmaceutical applications. Several MSs are conducting research with potential for agricultural applications, mainly in the area of resistance to animal diseases.

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## **Executive Summary**

The EU regulatory framework for biotechnology, which covers the approval process for marketing and environmental release, applies to both plants and animals. Regulatory structures and procedures for animal biotech at the Member State (MS) level largely parallel those for plant biotech, although some MSs have not yet developed their own regulatory frameworks. At present, there are no reports of commercial applications of animal biotech in the EU, nor have there been any notifications of food use. With regard to research, EU legislation covers in vitro laboratory testing. MSs have latitude to formulate their own policies for animal biotech research beyond the in vitro stage. Indeed, MS approaches to research vary widely, with most permitting confined projects for medical or pharmaceutical applications. Several MSs are also conducting research with potential for agricultural applications, mainly in the area of resistance to animal diseases.

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## **I. - POLICY**

### **A. EU Regulatory Framework**

The EU-27 regulatory framework for biotechnology events covers both plants and animals. The approval procedure is the same for Genetically Engineered (GE) animals as for GE plants. Biotech events [known in the EU as “Genetically Modified Organisms (GMOs)”], either for placing on the market or for release into the environment, are subject to the regulatory framework described in the annual 2009 EU-27 Consolidated Plant Biotech Report. Current EU biotechnology legislation, including [Directive 2001/18](#) [1] and [Regulation 1829/2003](#) [2] on biotech food and feed and [Regulation 1830/2003](#) [3] on traceability and labeling of GE products, covers both biotech plants and animals. The only exclusion to this legislation is for humans. Annex Ib of the Directive excludes mutagenesis from the GE definition.

[Directive 2009/41/EC of the European Parliament and of the Council](#) [4] regulates the contained use of “GMOs” in laboratories and industry. It covers micro-organism as well as animal and plant cells in culture. The Directive further requires that the approval procedure of the MS competent authorities include an assessment of confinement conditions for the whole life cycle. As all GE organisms start at the cell level in vitro, they are therefore covered by this Directive. Once modified and developed into fertile plants or animals, MSs have regulatory responsibility.

Notifications on deliberate releases and placing on the EU market of GE animals are published on the [GMOinfo database](#) [5] of the Joint Research Centre (JRC) of the European Community in the section “Organisms Other than Plants”. Currently this database only lists projects regarding research for medical/pharmaceutical purposes.

In addition to the types of impediments faced by plant biotechnology, differences in EU and U.S. patent legislation could also eventually lead to trade complications. The European Forum of Farm Animal Breeders (EFFAB) provides a [comparison](#) [6] between EU and U.S. patent legislation.

In view of increasing political sensitivity about GE technology in general and GE animals in particular, EFSA has created two new working groups on environmental and human health risk assessment [7]. There are indications that these working groups intend to install additional subgroups specifically dealing with GE fish, GE insects, GE mammals and GE birds. Draft guidance documents are reportedly scheduled for food/feed safety of GE animals by the end of 2009, environmental risk assessment of GE fish by the end of 2010, and for other GE animals by the end of 2011.

[1] <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:106:0001:0038:EN:PDF>

[2] <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0001:0023:EN:PDF>

[3] <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0024:0028:EN:PDF>

[4] <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:125:0075:0097:EN:PDF>

[5] <http://GEOinfo.jrc.ec.europa.eu>

[6] <http://www.effab.info/themes/patents/patent-watch>

[7] [http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa\\_locale-1178620753812\\_WorkingGroups4531.htm](http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa_locale-1178620753812_WorkingGroups4531.htm)

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## B. Activity on GE Animals in International Organizations

The EU and all MSs are members of the World Organization for Animal Health ([OIE](#)) [8] and [Codex Alimentarius](#) [9]. The EU and all MSs are also a party to the [Cartagena Protocol on Biosafety](#) [10].

In these fora, Austria strongly opposes GE animal use for agricultural purposes. France supports strict confinement and traceability of GE animals in its representations at OIE. In the Codex Alimentarius Task Force Biotechnology, the Dutch Government has requested attention to the ethical implications of using GE animals.

## C. Member States Policies

In EU MSs, national regulations and competent authorities regulating GE animals are generally the same as those regulating GE plants.

**Austria:** The Austrian Federal Ministry of Health is the leading competent authority for GE organisms including animals. It is responsible for contained use and deliberate release applications

from industry and research institutions except universities. The Federal Ministry of Science and Research is responsible for contained use and deliberate release applications from universities. The Federal Ministry of Agriculture, Forestry, Environment and Water Management is asked to comment in case of deliberate release and in case of placing products on the market. The Austrian Gene Technology Act (“Gentechnikgesetz 1994” and amendments) regulates genetic engineering of all organisms including animals.

**Belgium:** The Federal Belgian Government has joint responsibility with the two Belgian Regions, Flanders and Wallonia, for authorization of the use of GE animals. The Service of Biosafety and Biotechnology has a coordinating role and advises the government about the safety of using GE animals.

**Bulgaria:** No legislation or regulations exist regarding this topic, with respect to either implementation and/or executive authority. When such regulations are put in place, they will likely be under the authority of the National Vet Office, Ministry of Agriculture and Foods.

<sup>[8]</sup> [http://www.oie.int/eng/en\\_index.htm](http://www.oie.int/eng/en_index.htm)

<sup>[9]</sup> [http://www.codexalimentarius.net/web/index\\_en.jsp](http://www.codexalimentarius.net/web/index_en.jsp)

<sup>[10]</sup> <http://www.cbd.int/biosafety/>

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**Czech Republic:** GE animals are regulated in the same way as any other genetically engineered organisms in the Czech Republic. The basic national legal instrument is Act No. 78/2004 Coll., on the use of “genetically modified organisms and genetic products”, as amended by the Act No. 346/2005 Coll., with the implementing Decree No. 209/2004. It has been in force since February 2004. The competent authority handling the notifications and regulating the use of biotech products in the Czech Republic is the Ministry of the Environment. It cooperates with the Ministry of Health on risks for human health and with the Ministry of Agriculture on agricultural risk, animal health, crops and feeds. An expert advisory body to the Ministry of the Environment is the Czech Commission for the Use of GE products and Genetic Products, which consists of scientists, representatives of administrative authorities and NGOs. The competent authority on state supervision of the use of GE products is the Czech Environmental Inspectorate. The projects using GE animals that have been authorized in the Czech Republic so far fall under the scope of contained use. The authorized GE animals are classified as risk category 1 or 2 (minimal risk). Authorisation process: The entity that intends to use GE animals notifies the Ministry of the Environment. The notification must include the risk assessment, description of proposed containment measures and handling of the GE products including their transport, storage and disposal of waste.

**Finland:** Genetic engineering of all live organisms is regulated under the Gene Technology Act 377/1995 and the Gene Technology Decree 821/1995. The Board for Gene Technology is the competent authority for GE animals in Finland. The Board consists of a chairman, a vice chairman and five members who represent the Ministry of Trade and Industry, the Ministry of Agriculture and Forestry, the Ministry of Social Affairs and Health, and the Ministry of the Environment. Anyone wanting to use GE animals in contained conditions must apply for approval by the Board for Gene Technology. The National Supervisory Authority for Welfare and Health, under the Ministry of Social Affairs and Health, is responsible for the control of GE animal activities.

**France:** The French biotech bill of June 2008 regulates GE products in France, and the national authority evaluating GE products is the High Biotech Council, composed of a scientific committee and a socio-economic committee. The French Ministry of Agriculture is the competent authority for open-field testing, and would be charged to provide authorizations, following the approval of the French Ministry of Environment. However, there is currently no open field testing of transgenic animals in France. Regarding placing on the market, GE animals produced for food are regulated under the 1829/2003 regulation, while GE animals not produced for food are regulated under the 2001/18 Directive. Under this Directive, the French Ministry of Agriculture would be charged to review dossiers and provide written final consent, following agreement by the French Ministry of Environment. To date, there is no dossier pending approval.

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**Germany:** The German Genetech law is an umbrella law regulating any kind of genetic engineering of live organisms including plants, animals, fish, insects, bacteria etc. Requests for approval for research and development work with genetically engineered organisms, including GE animals, should be directed to the competent authorities of the German Laender (states). However, permission can only be granted when the scientific committee (Zentrale Kommission fuer Biologische Sicherheit - ZKBS) of the Federal Office for Consumer Protection and Food Safety (BVL) supports the application. The competent authority for regulating GE animals for food or feed consumption is the Bundesamt fuer Verbraucherschutz und Lebensmittelsicherheit (Federal Office of Consumer Protection and Food Safety) under the supervision of the Federal Ministry of Food, Agriculture and Consumer Protection. Risk assessment for GE animals for food or feed use is carried out by the Bundesinstitut fuer Risikobewertung (Federal Institute for Risk Assessment).

**Greece:** The GE animal approval process is similar to that followed for GE crops. A Permanent National Scientific Committee on Biotechnology operates under the Ministry of Environment, which is the competent authority. Members of the permanent committee are Ministry of Agriculture, Food Control Agency, Ministry of Health, Ministry of Development and Commerce, and university professors in biotechnology. Occasionally a parallel permanent Committee on Bioethics operates. Representatives of the Orthodox Church of Greece, NGOs, consumer organizations and academics are selected and/or invited to participate and present their views. Final decisions on approvals are taken on a “political basis” by the Ministries of Environment and Agriculture and rarely solely on scientific evidence, even if the permanent Scientific Biotech Committee advocates approval. The responsible government agency to be involved in GE animal research is the National Agricultural Research Foundation (NAGREF), under the Ministry of Agriculture, in cooperation with the National Secretariat for Research and Technology (under the Ministry of Development & Commerce).

**Hungary:** All kinds of genetic engineering (plant, microbe and animal) are regulated by the same (several times amended) XXVII./1998. Act on Biotechnology. Depending on the subject to be regulated, the competent authority is the Ministry of Agriculture, Ministry of Environment, or Ministry of Health. The inter-departmental body which receives and evaluates GE applications is the Gene Technology Committee. GE animal research programs have so far been confined to authorized biology laboratories. These ‘closed system’ research programs do not need to be listed and evaluated by the Gene Technology Committee, and approved by the corresponding competent authority (as is the case for open field tests of GE plant varieties).

**Ireland:** If GE farm animals were to be commercialized, they would be governed by the same EU regulations on releases to the environment, novel foods and labeling regulations as biotech plants. The regulations were deliberately written to cover both plants and animals.

**Italy:** In Italy, public and private bodies need to submit applications to the Ministry of Health in order to start research on GE animals. These animals are treated like experimental animals, in terms of applicable legislation. In general, Italy has implemented, through national legislation, the whole series of EU Directives relevant for gene technology, for both plants and animals (including micro-organisms). Applications are generally registered by the Ministry of Health.

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**The Netherlands:** In the Netherlands, organizations that want to use GE animals for medical research need to request a license from the Dutch Ministry of Agriculture. The Dutch Committee on Animal Biotechnology assesses all incoming license requests.

**Poland:** There is no separate legislation or regulations on GE animals in Poland. Polish legislation on GE animals is based on the Polish Law on “Genetically Modified Organisms” dated June 22, 2001 (updated May 21, 2003) addressing mainly genetically engineered plants. The Ministry of Environment is responsible for oversight of existing biotechnology regulations. The General Veterinary Inspectorate of the Ministry of Agriculture is not aware of any regulations specific to GE animals in Poland. The Department of Food Safety and Veterinary of the Ministry of Agriculture is waiting for directives or position of the EC to start working on regulations regarding GE animals in Poland. The Ministry of Environment prepared draft biotech legislation, which includes regulations regarding GE animals, but it is still being discussed at the Ministry level and has yet not been sent to the Parliament. However, due to the national discussion on GE plants and new legislation prepared by the Ministry of Environment, few Parliamentarians are planning to discuss GE animals. This is a very political issue and the Ministry’s legislative work will be determined by the political environment.

**Romania:** There is no national legislation specifically governing activities on GE animals. Nevertheless, the EU Directive 90/219 transposed through Emergency Ordinance 44/2007, and approved through Law 3/2008, covers the contained use of “genetically modified micro-organisms”. In addition to the above Emergency Ordinance, the Ministry of Environment published two orders: Order 973/2008 concerning the registry of activities of contained use of “genetically modified micro-organisms”, and Order 439/2009 establishing the forms accompanying the notifications for contained use of “genetically modified micro-organisms”. The competent authority is the National Agency for Environment Protection, while the Ministry of Agriculture, Forests and Rural Development, the Veterinary and for Food Safety National Authority, the Ministry of Public Health, and National Guard for Environment are the relevant authorities in this field. The Biosafety Commission, formed in 2008, assesses, at the request of the competent authority, all notifications from the scientific standpoint and issues a scientific resolution.

**Slovakia:** There is no special legislation or administrative institution. GE animals are considered genetically engineered organisms and relevant legislation applies (i.e., the Act on GMOs no. 151/2002 amended by the Acts no. 587/2004, no. 77/2005, no. 100/2008 and no. 515/2008).



**Spain:** GE animal authorities would be the same as GE crop authorities. There are two relevant institutions in the biotech decision-making process, the National Biosecurity Commission and the Interministerial Council. The National Biosecurity Commission includes representatives from the national administration, the autonomous communities and experts. The Interministerial Council members are representatives from the Ministry of Environment and Rural and Marine Affairs (MARM), the Ministry of Health and Social Policies, the Ministry of Industry, Tourism and Trade, the Ministry of Science and Innovation and the Ministry of Internal Affairs. This Council is chaired by the General Director of Rural Sustainable Development, from the MARM. The Interministerial Council is an advisory body responsible for approving confined use, voluntary release and commercialization of biotech products.

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**Sweden:** The Swedish Board of Agriculture is the competent authority for GE animals. The National Board of Fisheries is the authority responsible for the contained use, deliberate release and placing on the market of genetically engineered aquatic organisms. Genetic engineering of all live organisms is regulated in chapter 13 of the Swedish Environmental Code, which is supplemented by a number of ordinances and regulations. The use of GE animals is regulated in the Board of Agriculture's Regulations on the Use of "Genetically Modified Animals" (SJVFS 1995:33) and the National Board of Fisheries' Regulations on "Genetically Modified Aquatic Organisms" (FIFS 2004:2). The contained use of genetically engineered animals is regulated in SJVFS 2000:271. Anyone using GE animals in contained conditions (e.g. in animal houses or similar facilities) must apply for consent to use the premises and then notify the Board of Agriculture of the intended contained use. Corresponding requirements apply to aquatic organisms, which are the responsibility of the National Board of Fisheries. Industry and universities developing GE animals also need approval from the Swedish Work Environment Authority. In addition, approval is needed from an animal ethics committee.

**United Kingdom:** If GE farm animals were to be commercialized, they would be governed by the same EU regulations on releases to the environment, novel foods and labeling regulations as biotech plants. The regulations were deliberately written to cover both plants and animals.

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## **II. – COMMERCIAL USE OF GE ANIMALS**

To date, there are no commercial applications approved for GE animals for food / feed use in any of the EU MSs, and no notification of the use of GE animals for food use or other agricultural use has been filed in the EU. However, some GE animals or products are used for confined medical and pharmaceutical research purposes, most of them transgenic rodents.

## **III. – RESEARCH AND DEVELOPMENT**

### **A. European Perspectives**

The oversight of biotech research is the competence of MSs. [Directive 2009/41/EC of the European Parliament and of the Council](#) [11] regulates the contained use of genetically engineered organisms

in laboratories and industry.

The [Molecular Biology and Genomics Unit](#) [12] of the Joint Research Centre (JRC) of the European Community provides scientific and technical support for policy development under the EC regulatory framework for genetically engineered organisms and for the development of biotechnology expertise in areas relevant to health and consumer protection.

European Commission-sponsored animal genetics platform: On March 2, 2006, a [Farm Animal Breeding and Reproduction Technology Platform](#) [13] (FABRE TP) was launched at the Paris International Farm Show, with funding from the 6th Research Framework Program of the European Union (FP6). At the launch, FABRE TP's goals were communicated in a Vision Paper "[Sustainable Farm Animal Breeding and Reproduction: a Vision for 2025](#)" [14]. This Technology Platform was set up to coordinate research in the domain of animal genetics among various stakeholders in the public sector and industry across EU MSs. Its goal is to tackle major issues concerning sustainability, animal breeding and reproduction in Europe. On May 11, 2007, this resulted in a [Strategic Research Agenda](#). [15]

At the same time as the FABRE TP launch, [Code-EFABAR](#), [16] a code of best practices for the breeding of farm animals, was presented. This code, which was the output of another EU-funded project, is intended to become the standard instrument in Europe for defining and implementing best practices in farm animal breeding.

[11] <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:125:0075:0097:EN:PDF>

[12] <http://bGEo.jrc.ec.europa.eu/>

[13] [www.fabretp.org](http://www.fabretp.org)

[14] <http://www.fabretp.org/images/vision.fabretp.def1.pdf>

[15] [http://www.fabretp.org/index.php?option=com\\_content&task=view&id=29&Itemid=49](http://www.fabretp.org/index.php?option=com_content&task=view&id=29&Itemid=49)

[16] [www.codeefabar.org](http://www.codeefabar.org)

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## B. Member States Research and Development Projects

Most MSs conduct projects on GE animals, generally for medical or pharmaceutical applications. In Hungary, Italy and the UK, some research projects have agricultural applications. Reportedly, there are no projects conducted in Bulgaria, Greece, Romania or Ireland.

**Austria:** There is no research on GE animals for the food market in Austria. GE laboratory animals are used for medical and pharmaceutical research mainly at universities and as gene farming for cancer medication.

**Belgium:** GE animals are authorized for use as laboratory animals for medical research at universities and academic hospitals.

**Czech Republic:** In the Czech Republic, GE laboratory animals (primarily mice and rats) are used



for research purposes in universities and research institutions. These animals serve mostly as subjects in genetic, pharmaceutical and medical studies.

**Finland:** There is no research on GE animals for food production in Finland. However, GE animals, mainly mice, are used in medical research, mainly at universities.

**France:** The French public agricultural research institute L'Institut National de la Recherche Agronomique (INRA) does some research on various GE animals. Due to the strong opposition by the public and policy makers, INRA does not envision, in the short to medium term, experimenting or developing large commercial animals (including cattle, hogs and poultry) except for medical/human health research.

The following are examples of French animal biotech research projects.

- GE fish are developed for transparency to observe the impact of gene modification on organs and animal growth. GE mice are developed to evaluate several gene modifications on mammal growth and behavior. The research is mainly limited to the gene expression and the on-demand activation of genes. The ultimate aim would be, at a later stage, to transfer findings on mice to larger animals.
- GE mice for biomedical purposes (mainly in the cancer research field) by INRA with human health research institutes.
- Transgenic rabbits: production of human therapeutic proteins and vaccines in their milk.

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**Germany:** According to BVL, GE animals or products thereof are currently not in the commercial market in Germany. There are also no known research projects on GE animals for the food market. Research is done exclusively for medical purposes.

The following are examples of German animal biotech research projects.

- Mice, cattle, hogs: Lentivirus gene transfer into cells of different species
- Hogs: rearing of transgenic hogs containing replication defect lentiviruses
- WHHL rabbits: evaluation of new vectors and gene-transfer procedures for therapy of familial hypercholesterolemia
- Hogs: rearing of transgenic hogs for reproduction with conventional hogs
- Hogs: for xenotransplantation
- Sheep, cattle: recombinant plasmids containing the human factor VIII and IX genes should be micro-injected in oocytes of sheep and cattle.
- Cattle: transgenic cattle for the production of lactase as a recombinant protein in the mammary gland to reduce the expression of lactose.
- Hogs, rabbits: the hogs express the marker gene GFP in all somatic cells and the rabbits express the neomycin marker gene in the germ line cells. These animals should yield blastocysts to isolate embryonic stem cells.
- Rabbits: phenotypic characterization of transgenic rabbit models for the human Long-QT syndrome type 1 and 2 in vivo and in vitro
- Rabbits: to produce humanized polyclonal antibodies

- Frogs (Xenopus): identification of morphoregulatory effects on proteins in Xenopus
- Zebra fish (Brachydanio rerio): chromosome recombination with FLP-recombinase of *Saccharomyces cerevisiae*
- Zebra fish: establish a line of myc-transgenic zebra fish to produce a tumor model equal to the Burkitt Lymphoma in humans
- Zebra fish: the zebra fish contain the gene for the green fluorescent protein (GFP) of *Aequorea Victoria*
- Fish teleosts: carp, mouse or human genes to influence cell growth or cell differentiation processes should be inserted in the cytoplasm of two-cell embryos of medaka fish
- Fish: production of stable fish lines for the purpose of identification development relevant genes with the assistance of a GFP reporter system

**Hungary:** Several biotechnology companies, university knowledge centers, and bio-incubators located in four academic towns are conducting research on GE animals in Hungary.

The following are examples of Hungarian animal biotech research projects.

- Transgenic mouse model to study a bovine gene with economic impact
- Producing high-value added bio molecules in milk of transgenic rabbits
- Second generation transgenic animals
- Humanized Mice Transporter Models
- Nuclear replacement (“cloning”) methods in mouse: test of safety & reliability for generation of transgenic models

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**Italy:** There is research conducted by both public and private entities (universities, labs, research institutes, etc). This research relates mainly to mice and other lab animals for medical and pharmaceutical purposes.

The following are examples of Italian animal biotech research projects.

- GE swine targeted at the production of organs for transplants
- GE cattle for resistance to BSE

**The Netherlands:** GE animals are authorized for use as laboratory animals for medical research at universities and academic hospitals. Annually in the Netherlands, 15 to 20 licenses are granted.

**Poland:** Research on GE animals is very limited. It is carried out in three research centers in Poland: Institute of Animal Breeding in Balice (Krakow), Institute of Animal Genetics in Jastrzebiec (Warsaw) and Agricultural University (Poznan). Each research project must be approved by the Ministry of Environment.

The following are examples of Polish animal biotech research projects.

- Transgenic swine, which organs are used in transplantology
- GE rabbits.

**Slovakia:** There is research conducted in laboratories only on GE animals (mainly mice), and no research outside laboratories.

**Spain:** There is no known research or development of GE animals for the food market. The Ministry of Environment and Rural and Marine Affairs (MARM) keeps track of GE animals used in confined facilities and publishes a list on its web site. GE animals notified to the MARM from 1992 to the present are mice and hogs for medical purposes in universities, public and private research centers.

**Sweden:** There is no research on GE animals for food production in Sweden. However, GE animals, mainly mice, are used by universities and industry for biological, medical and biomedical research. At present, no research is going on in Sweden in regard to the genetic modification of aquatic organisms.

**United Kingdom:** There has been a great deal of GE animal research in the UK, mainly involving mice but, more recently, larger animals.

Following are examples of GE research projects at Roslin Institute and at the Cambridge University.

- GE sheep to make various pharmaceuticals in their milk.
- Lentiviral vectors to carry the modification making GE pigs and chickens, mainly for simple demonstration of the technology, such as expressing green fluorescent proteins.
- Variety of approaches to seek to make chickens resistant to avian influenza virus through genetic modification.